TRENDS IN NEW DRUG APPROVALS AND CLINICAL TRIAL PUBLICATIONS OVER A 2-DECADE INTERVAL

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ABSTRACT
Objectives: The volume of new data can affect the ability of healthcare practitioners to keep
up with advances in the literature pertaining to their specialty. This study used the
National Library of Medicine's PubMed database to identify all clinical trials in
four therapeutic areas (oncology, HIV, diabetes, and cardiovascular disease) during
the years 1993 through 2012. The PubMed database was searched to identify clinical
publications in the therapeutic areas of oncology, HIV, diabetes, and cardiovascular disease
during the same period.

INTRODUCTION
A consistent increase in the number of noninferiority clinical trial publications was
observed from 1993 through 2009. Increases in the publication of clinical trials continued
following enactment of new FDAAA/FDAMA laws. Future analyses should explore the reasons
for the continued increase and its potential effects on how clinicians maintain awareness of the
literature.

RESEARCH DESIGN AND METHODS
The US National Library of Medicine’s PubMed database was searched to identify all
clinical studies published in the therapeutic areas of oncology, HIV, diabetes, and cardiovascular disease
during the years 1993 through 2012. The PubMed database was searched to identify all clinical
trials in the therapeutic areas of oncology, HIV, diabetes, and cardiovascular disease.

RESULTS
On average, more NDAs and BLAs were approved during the fourth quarter of the year,
followed by the third quarter. The total number of NDAs and BLA approvals remained fairly
constant throughout the 20-year period. The number of cancer, HIV, diabetes, and cardiovascular clinical
trial publication increased steadily from 1993 through 2012. Collectively, these publications increased
by 136% from 1993 through 2012.

CONCLUSIONS:
As with total clinical trial publications, the number of annual oncology, HIV, diabetes,
and cardiovascular clinical trial publications increased steadily between 1993 and 2012.

OBJECTIVE
To examine historical trends in new drug approvals and publication of clinical trials

RESEARCH DESIGN AND METHODS
The FDA’s Drug Approval Report database was searched to identify original New Drug
Applications (NDAs) and Biological License Applications (BLAs) for NDAs and BLAs.

RESULTS
On average, more NDAs and BLAs were approved during the fourth quarter of the year,
with wide variations in approvals are apparent each quarter.

CONCLUSIONS
Although the number of drug approvals has not varied substantially over recent years,
the total number of clinical trials in the therapeutic areas of oncology, HIV, diabetes,
and cardiovascular disease increased by 317% in 2012 compared with 1993.

IMPLICATIONS
Despite relatively little change in the annual numbers of NDAs/BLAs year over year,
the continuing increase in clinical trial publications creates a need for:
– More consistent locations in publications that describe the methodology of trials and clinical
  evidence for each agent
– Identification of new tools or methods to ensure scientific information is reaching the audience
  through the media they use to acquire information
– Increased and more efficient engagement of the medical literature

REFERENCES
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